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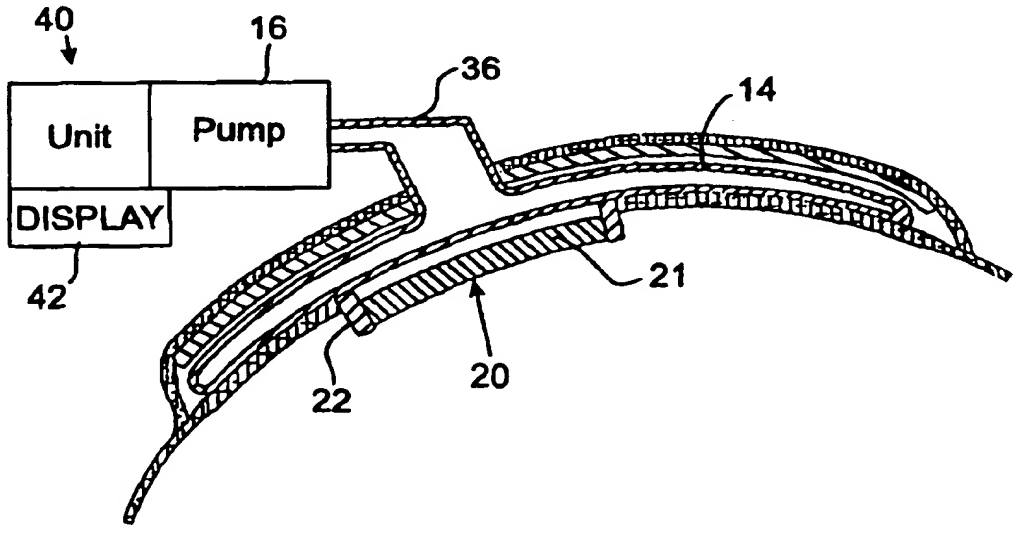

(57) Abstract

This invention is a blood pressure monitoring device comprising a cuff (12) with an improved sensor (20) incorporated into the cuff (12) for the purpose of providing increased accuracy and repeatability of the readings obtained. The cuff (12) is placed around the wrist of the user, rather than the upper arm, and comprises an internal bladder (14) localized to the area of the patient above the artery being monitored, and a sensor (2) that is positioned above the artery for measuring the blood pressure.

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IMPROVED BLOOD PRESSURE MONITORING CUFF

BACKGROUND OF THE INVENTION

Related Application

This application claims priority of co-pending United States provisional application serial no. 60/004,666 filed on October 2, 1995.

Field of the Invention

The present invention is generally related to blood pressure monitoring devices, and in particular to an improved blood pressure monitoring cuff for providing increased accuracy and repeatability of blood pressure readings.

Description of the Related Art

In the past, there have been a number of portable blood pressure monitors that have been used to obtain the systolic and diastolic blood pressures, as well as the heart pulse rate of the user. The principal non-invasive blood pressure measuring device used today is an auscultatory system where a cuff pressure is applied to occlude a major artery, such as the brachial artery. In practice, an inflatable encircling cuff is placed around the arm and inflated to occlude the brachial artery to prevent flow of blood in the artery. As the pressure in the cuff is slowly lowered, permitting flow of blood in the artery, Korotkoff sounds are heard. The cuff pressure at which the first sound is heard is defined as the systolic pressure. The pressure in the cuff is then lowered further and the pressure in the cuff at which the sound fades is defined as the diastolic pressure.

However, it has been observed that the signal to noise ratio of the blood pressure sounds used in

auscultatory systems is low when a cuff is used on the upper arm of the patient. This is due to the presence of a large amount of fatty body tissue at the upper arm, particularly when compared to the fatty body tissue present at the wrist of the same user. However, doctors have preferred using the upper arm for the cuff in order to be closer to the source of pressure, namely the heart which is pumping the blood through the system.

A second occluding cuff technique uses palpation of the pulse rather than auscultation. In a palpatory system, as the occluding cuff pressure is slowly released, arterial pulsations are detected by palpation. The pressure level of the cuff at which the pulsations are first perceived is designated as systolic blood pressure. Diastolic blood pressure cannot be detected by palpation.

Another occluding cuff system uses the maximum and minimum oscillations of arterial blood pressure referenced to cuff pressure as indications of systolic and diastolic blood pressure, respectively. In addition to being an intermittent, occlusive technique, the measurements thus obtained are likely influenced by the volume of the limb around which the cuff is applied. Diastolic blood pressure is measured in the height of a column of mercury in millimeters that is necessary to close off the artery. The systolic blood pressure is the millimeters of mercury that is necessary to first permit the sound of blood to pass through the artery after it has been completely closed. The blood pressure is the force that is exerted against the walls of the blood vessels by the circulating blood. Blood passing from the heart through the lungs has only about one-sixth of pressure of blood that is forced

out over the body through the aorta. However, the pressure of blood passing from the heart through the lungs is sufficient to assure flow through the multitude of capillaries in the walls of the lungs.

The maximum pressure in the arteries is related to the contraction of the left ventricle of the heart, and is referred to as the systolic pressure. The minimum pressure in the arteries just before the heartbeat which follows is the diastolic pressure. The pressure of the blood in the smaller arterioles and in the capillaries is much less than in the arteries.

The average systolic blood pressure in young adult men is about 120 mm of mercury; and the diastolic pressure is about 80 mm Hg. These figures are frequently stated as 120/80, or 120 over 80. Pressures in this range usually are adequate to provide the body with an adequately circulating supply of blood without placing any undue strain on the walls of the blood vessels. Considerable normal variations from these values may occur, and values as much is 20 mm below those, stated may be encountered in healthy individuals.

A number of factors work together to maintain the blood pressure within normal limits. The pumping action of the heart itself is of major importance, as is the competency of the heart valves in closing so that no leakage occurs back from the arteries into the heart chambers. The elasticity of the arteries also influences the pressure. The resistance that the blood meets in the smaller blood vessels causes considerable variation. The amount of blood in the circulatory system and its viscosity also are factors. When any of these variables change

markedly, the blood pressure may be increased or decreased. These pressure changes, in turn, may produce abnormalities in the structure and function of the heart and blood vessels. The most common variation in the blood pressure is an increase in its magnitude, which is referred to as hypertension, or high blood pressure.

At present there exists an apparatus for measuring the blood pressure (sphygmomanometer) comprising of a rubber-bag cuff which is wrapped around the upper arm and is inflated by a hand bulb. The cuff is connected by rubber tubing to a measuring device which is either a sealed column of mercury or a spring scale. Sufficient pressure is pumped into the rubber-bag cuff to compress the brachial artery in the upper arm. A stethoscope is applied over the artery below the cuff and air is gradually allowed to escape from the cuff until the pulse can be heard. The reading on the scale or column of mercury at this point indicates the systolic pressure or the highest pressure in the arteries during contraction of the heart. The deflation of the cuff is continued, and that point on the scale when the last sound of the disappearing pulse is heard is the diastolic pressure, or lowest pressure in the artery during diastole, or relaxation of the heart muscle between beats. The blood pressure in such an apparatus is obtained by auscultatory techniques, namely listening with a microphone pick-up, to the sounds of blood flow, and at the same time measuring the peaks of the pulse wave in order to obtain the number of beats per minute of the heart or pulse. These are all done by well-known and conventional methods.

U.S. Patent No. 4,993,422 issued to Hon et al. on February 19, 1991, discloses an apparatus that is attached

to the wrist of a patient that is not used in association with an inflatable bladder. The apparatus has an isolation ring for isolating a portion of cutaneous tissue in contact with a pressure transducer in order to obtain a measurement of the cutaneous pressure of a patient. Such an isolation ring had a relatively small diameter and was not used for the conventional monitoring of arterial blood pressure.

The prior systems of measuring blood pressure permit the arm of the patient to move during measurement and prevent the application of a sensor to be at the precise point of the arm that has the greatest signal. Thus, when there are repeated measurements of the blood pressure of a patient, the present invention reduces the variability in the measurements that is typically inherent due to different starting parameters for each measurement.

SUMMARY OF THE INVENTION

The present invention is directed to a blood pressure monitoring cuff that provides increased accuracy and repeatability of the readings obtained. In the preferred embodiment, the blood pressure monitoring cuff of the present invention is placed around the wrist of the user, rather than the upper arm as is typically the case. However, it is appreciated that the blood pressure monitoring cuff of the present invention may also be placed around the upper arm of the user. The blood pressure monitoring cuff comprises an internal inflatable bladder and a sensor that is positioned above the radial artery in the lower arm near the wrist. As the signal to noise ratio is low in a cuff which has a large volume of air entrapped between the walls of the inflatable cuff, it is difficult to correlate the signal noise to the noise found in the

cuff. In the present invention, in order to increase the signal to noise ratio, the volume of air required to tension the cuff has been reduced and a ring is included at the inner surface of the cuff that comes into contact with the wrist of the user so that the signal from the blood pressure that is heard by the auscultatory pick-ups are magnified, permitting more accurate reading of the signal.

The present invention is an improvement over conventional blood pressure measuring devices, the improvements including, but not limited to, the following:

1. The measuring point of the present invention is closer to the wrist where the flesh is less fatty than the upper arm, resulting in a better reading;
2. The improved sensor of the present invention has a ring to isolate a portion of tissue to magnify the signal that is being heard by the auscultatory pick-ups resulting in a more accurate reading;
3. The improved inflatable cuff of the present invention requires less air than those in the past because it has less volume than a cuff surrounding the upper arm and because it uses an improved sensor, so signal to noise ratio is increased;
4. The improved cuff and sensor of the present invention can be used with the same signal reading instruments as those used for conventional cuffs; and
5. The wrist stabilizer extension of the present invention keeps the arm of a patient

stable and still to reduce noise created from arm movement.

OBJECTS OF THE PRESENT INVENTION

It is an object of the present invention to provide an improved blood pressure monitoring cuff that is simple to use.

It is another object of the present invention to provide an improved blood pressure monitoring cuff that is reliable.

It is a further object of the present invention to provide an improved blood pressure monitoring cuff that is accurate.

It is yet another object of the present invention to provide an improved blood pressure monitoring cuff that is more repeatable.

It is an object of the present invention to provide an improved blood pressure monitoring that is inexpensive.

These and other objects of the present invention will become apparent from a review of the accompanying drawings and the detailed description of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a top perspective view of the improved blood pressure monitoring cuff of the present invention shown in the open position.

FIG. 2 is a sectional view of the improved blood pressure monitoring cuff of the present invention along lines 2--2 of Figure 1 illustrating the sensor and the inflatable bladder of the present invention.

FIG. 3 is a side perspective view of the improved blood pressure monitoring cuff of the present invention

shown attached to the lower arm of a patient.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring to Figures 1-3, the blood pressure monitoring device 10 of the present invention is shown and generally referred to by the number 10. The blood pressure monitoring device 10 comprises a cuff 12 for surrounding the lower arm of a patient near the wrist. The cuff 12 has an interior surface 18 which is placed against the skin of the patient. The cuff 12 has an internal bladder 14 which is inflated with air by a pump 16 to tension the cuff to compress an artery of the patient, such as the radial artery in the human wrist. The internal bladder 14 has a smaller volume than bladders of conventional cuffs because the cuff 12 encircles the lower arm of the patient which has a smaller circumference than the upper arm. As a result of the smaller volume, the internal bladder 14 requires less air than conventional bladders in blood pressure cuffs that are applied to the upper arm of a patient and is easier to inflate to the minimum pressure needed to compress the artery being monitored.

Referring to Figure 2, in the preferred embodiment, the bladder 14 is localized in the area of the cuff 12 that is to be in contact with the surface of the patient's forearm above the radial artery. A sensor 20 is located on the interior surface 18 of the cuff 12 and is positioned to correspond with the radial artery of the patient when the cuff 12 is placed around the arm of a patient as shown in Figure 3. The sensor 20 has a membrane 21 that may be in contact with the exterior of the internal bladder 14 to communicate signals obtained from the artery being monitored to the monitoring unit 40, described below,

via the internal bladder 14. For example, the sensor 20 may be of the auscultatory type which is capable of detecting the sounds of blood flow, and at the same time measuring the peaks of the pulse wave in order to obtain the number of beats per minute of the heart or pulse. The sounds of blood flow and pulse wave peaks are conducted to the monitoring device 40 via the internal bladder 14 and are detected by auscultatory pick-ups. The membrane 21 is preferably made of a mylar material and is surrounded by a flexible ring 22 which is preferably made of rubber, that comes into contact with the patient's skin and encloses a portion of the patient's skin so that the signal from the blood pressure that is heard by the auscultatory pick ups are magnified, permitting more accurate reading of the signal.

Referring to Figure 3, extending from the cuff 12 is an arm board 30 for supporting the patient's arm and holding the patient's arm in stable position in order to further eliminate any noise interference of the blood pressure monitoring caused by arm movement. The arm board 30 has one end that is removably attachable to the cuff 12 and has another end that terminates in a hand pad 32 which may be a sponge or other flexible material. The hand pad 32 fits into the patient's hand during use of the blood pressure monitoring device 10 and functions to maintain the patient's hand in the appropriate position during blood pressure monitoring of the radial artery with the sensor 20.

It is appreciated that while the arm board 30 is shown with the wrist extended at an angle, the arm board 30 may have any other angle, or no angle at all, as long as

the patient's arm is stabilized and the patient is comfortable.

The cuff 12 is made of a flexible material such as cloth or nylon and is wrapped around the lower arm of the user. The cuff has a narrow end 44 that is fed into a loop member 46 for tensioning the cuff 12 about the lower arm of the patient. Once the suitable tension of the cuff 12 about the lower arm of the patient is achieved, the narrow end of the cuff 12 is secured to the remainder of the cuff 12 with hook and loop fasteners 46a and 46b, such as Velcro, to provide a stable coupling of the cuff 12 to the lower arm of the patient. It is appreciated that the cuff of the present invention may also be placed around the upper arm, or other suitable limb of a patient, without departing from the scope of the invention.

Referring again to Figures 1 and 2, the bladder 14 and the sensor 20 are coupled via tubing 36 to a blood pressure monitoring unit 40 capable of reading the signals detected by the sensor 20. The monitoring unit 40 is of the type commonly used for conventional auscultatory blood pressure monitors. One such monitor is commercially available from the Omron Corporation. The monitor 40 has a display 42 for displaying the signals detected from the sensor 20 in conventional units such as mm Hg.

While the preferred embodiment has been described in detail, it is recognized that other variations of the present invention may be devised without departing from the present concept.

What is claimed is:

1. A blood pressure monitoring device, comprising:

a cuff for surrounding a limb of a patient, said cuff having an inflatable bladder localized to a portion of the cuff to be placed in contact with the skin of a patient above an artery to be monitored, said bladder having an aperture for inflation and deflation of said bladder;

sensor means for detecting blood pressure in an artery, said sensor means having an output responsive to changes in pressure of an artery;

said cuff capable of holding said sensor means against the skin of a patient above an artery to be monitored; and

monitoring means for reading said output from said sensor means, said monitoring means being coupled to said bladder.

2. The blood pressure monitoring device of claim 1 in which said sensor means is positioned to correspond with the radial artery of the wrist of a patient when said cuff is placed around the forearm of a patient.

3. The blood pressure monitoring device of claim 1 in which said sensor means comprises an auscultatory sensor capable of detecting the sounds of blood flow.

4. The blood pressure monitoring device of claim 1 in which said sensor means includes means for measuring the peaks of a pulse wave.

5. The blood pressure monitoring device of claim 1 in which said sensor means has a membrane made of a mylar material.

6. The blood pressure monitoring device of claim 5 including a ring surrounding said sensor means, said ring making contact with the skin of the patient enclosing an area of skin to be monitored by said sensor means.

7. The blood pressure monitoring device of claim 1 stabilizing means for holding a patient's arm in a stable position.

8. The blood pressure monitoring device of claim 7 in which said stabilizing means is an arm support extending from said cuff.

9. The blood pressure monitoring device of claim 8 in which said arm support has one end that is removably attachable to said cuff and has another end that terminates in a hand pad which fits into the patient's hand during use of the blood pressure monitoring device, said hand pad maintaining the patient's hand in selected position during blood pressure monitoring of the radial artery.

10. The blood pressure monitoring device of claim 8 in which said arm support includes means for extending the wrist of a patient an angle.

11. The blood pressure monitoring device of claim 1 including means for securing the cuff about the lower arm of the patient.

12. The blood pressure monitoring device of claim 1 in which said monitoring means including displaying means for displaying said output from said sensing means.

13. The blood pressure monitoring device of claim 1 including a pump for inflating said bladder.

14. A blood pressure cuff for surrounding a limb of a patient, said cuff having an inflatable bladder localized to a portion of the cuff to be placed in contact with the

skin of a patient above an artery to be monitored, said bladder having an aperture for inflation and deflation of said bladder.

15. The blood pressure cuff of claim 14 including means for securing the cuff about the lower arm of the patient.

16. The blood pressure cuff of claim 14 stabilizing means for holding a patient's arm in a stable position.

17. The blood pressure cuff of claim 16 in which said stabilizing means is an arm support extending from said cuff.

18. The blood pressure cuff of claim 17 in which said arm support has one end that is removably attachable to said cuff and has another end that terminates in a hand pad which fits into the patient's hand during use of the blood pressure cuff, said hand pad maintaining the patient's hand in selected position during blood pressure monitoring of the radial artery.

19. The blood pressure cuff of claim 17 in which said arm support includes means for extending the wrist of a patient an angle.

20. A blood pressure cuff for surrounding a limb of a patient, said cuff having an inflatable bladder localized to a portion of the cuff to be placed in contact with the skin of a patient above an artery to be monitored, said bladder having an aperture for inflation and deflation of said bladder and a sensor means for detecting blood pressure in an artery, said sensor means having an output responsive to changes in pressure of an artery.

21. The blood pressure cuff of claim 20 in which said sensor means is positioned to correspond with the radial

artery of the wrist of a patient when said cuff is placed around the forearm of a patient.

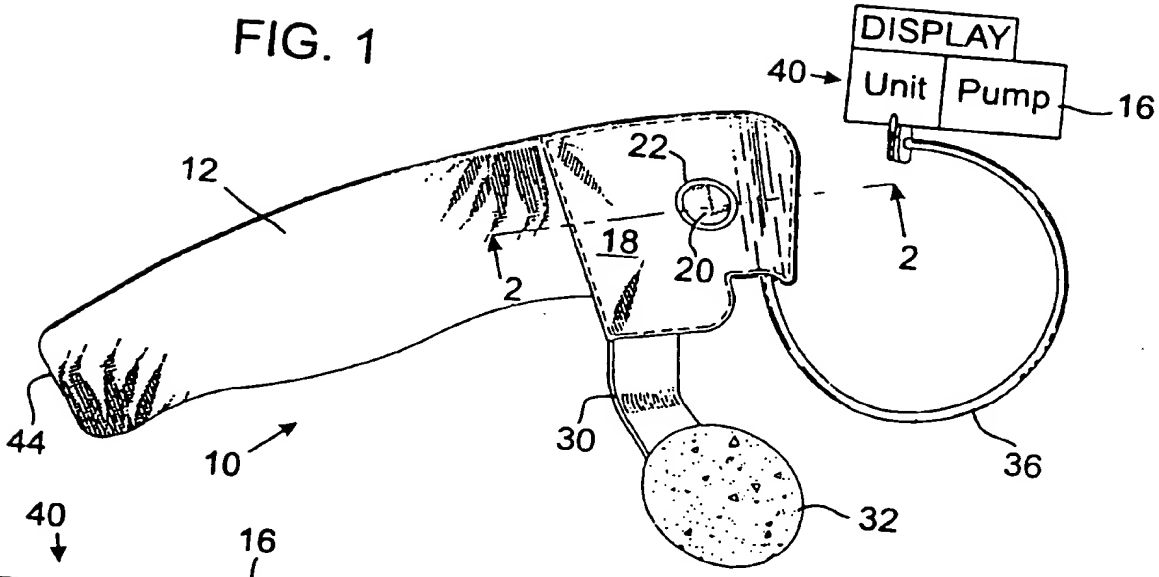
22. The blood pressure cuff of claim 21 in which said sensor means comprises an auscultatory sensor capable of detecting the sounds of blood flow.

23. The blood pressure cuff of claim 21 in which said sensor means includes means for measuring the peaks of a pulse wave.

24. The blood pressure cuff of claim 21 in which said sensor means has a membrane made of a mylar material.

25. The blood pressure cuff of claim 21 including a ring surrounding said sensor means, said ring making contact with the skin of the patient enclosing an area of skin to be monitored by said sensor means.

FIG. 1



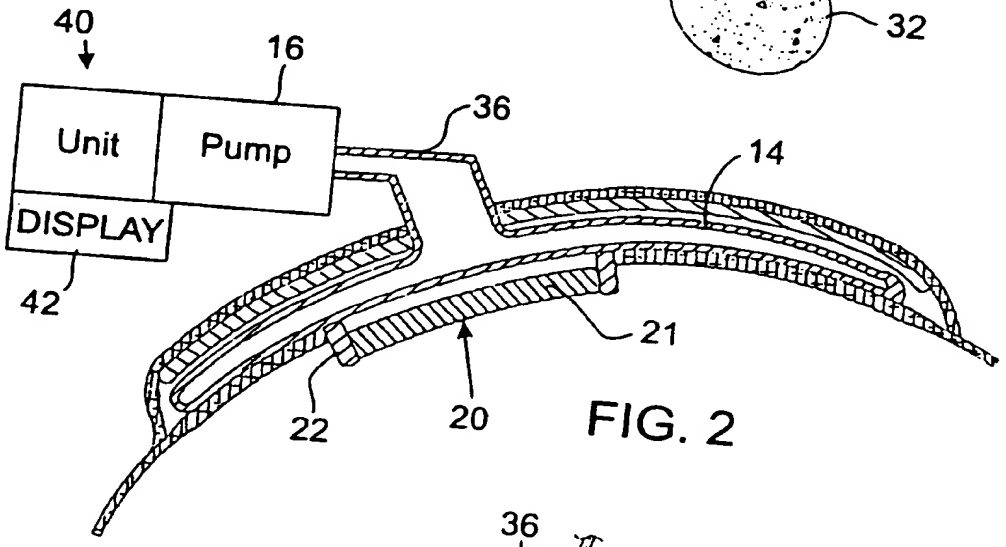


FIG. 2

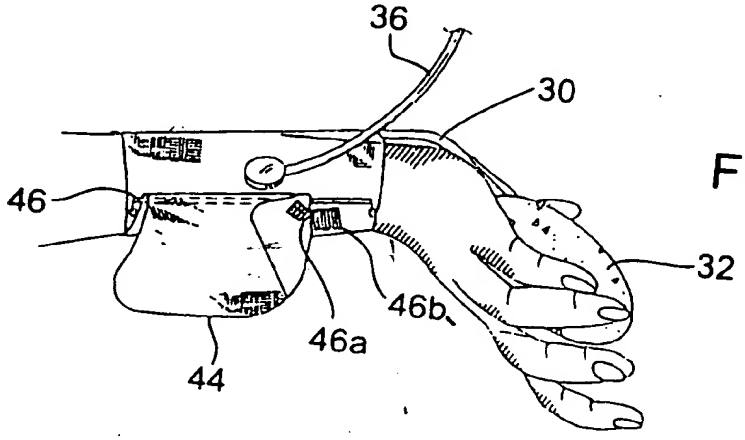


FIG. 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/15756

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 5/00;
US CL :128/686

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/672, 680-683, 686, 687, 690; 606/202

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,993,422 A (HON et al) 19 February 1991, entire document.	1, 2, 4, 7-21, 23-25.
X	US 4,890,625 A (SORENSEN) 02 January 1990, entire document.	1-3, 11-15, 20-22.
X	US 5,099,853 A (UEMURA et al) 31 March 1992, entire document.	1, 4, 5, 11-15, 20, 23.
X	US 3,603,304 A (MAIER) 07 September 1971, entire document.	14. 15.

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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